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EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

1647

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,086	<b>Applicant(s)</b> GALLAHER ET AL.	
	<b>Examiner</b> JON M. LOCKARD	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-44 is/are pending in the application.
- 4a) Of the above claim(s) 26,28,31,35,36,39,40,43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25,27,29,30,32-34,37,38,41 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 25-44 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Alignment</u>                 |

**DETAILED ACTION*****Election/Restrictions***

1. Applicant's election of Group I, claims 25, 27, 29-30, 32-34, 37-38, and 41-42, in so far as they are drawn to polypeptides of SEQ ID NOs:1 and 21 (encoded by SEQ ID NO:5), in the reply filed on 13 November 2007 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP §818.03(a)).
2. Claims 26, 28, 31, 35-36, 39-40, and 43-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 13 November 2007.
3. The restriction requirement is still deemed proper and is therefore made FINAL.

***Status of Application, Amendments, and/or Claims***

4. The response filed on 13 November 2007 has been entered in full. Claims 26, 28, 31, 35-36, 39-40, and 43-44 are withdrawn from further consideration as discussed above. Therefore, claims 25-44 are pending, and claims 25, 27, 29-30, 32-34, 37-38, and 41-42 are the subject of this Office action. It is noted that the elected invention is the polypeptide of SEQ ID NOs:1 and 21 (encoded by SEQ ID NO:5), and the claims have been examined to the extent that they read upon the elected invention.

### ***Sequence Rules***

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, the application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Specifically, amino acid sequences appear at pg 8 (Table 1) without an accompanying sequence identifier (i.e., SEQ ID NO: #). The instant specification will need to be amended so that it complies with 37 C.F.R. §1.821(d) which requires a reference to a particular sequence identifier (i.e., SEQ ID NO: #) be made in the specification and claims wherever a reference is made to that sequence (See M.P.E.P. 2422.04).

### ***Specification***

6. The disclosure is objected to because of the following informalities:

7. The Specification is objected to because Table 1 (pg 8) discloses amino acid sequences without the accompanying SEQ ID NO:.. The SEQ ID NO: may be inserted into the Table or the description of the Table.

### ***Claim Objections***

8. Claims 25 and 27 are objected to because of the following informalities: Claims 25 and 27 encompass non-elected inventions, e.g., SEQ ID NO:3, SEQ ID NO:9, SEQ ID NO:13, and SEQ ID NO:17 (claims 25 and 27); SEQ ID NO:23, SEQ ID NO:25, SEQ ID NO:27, and SEQ ID NO:29 (claim 25); SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15, and SEQ ID NO:19 (claim 27). Appropriate correction is suggested.

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9. Claim 32 is objected to because of the following informalities: Claim 32 is objected to as being duplicative of claim 30. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

10. Claim 37 is objected to because of the following informalities: typographical error, "10-8M" should read  $10^{-8}M$ . Appropriate correction is suggested.

11. Claims 41 and 42 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. While it is noted that claim 41 recites "wherein the nucleic acid sequence corresponding to the peptide is contained in a suitable nucleic acid vector for delivery into a cell, and wherein the vector contained in the cell permits expression of the polypeptide within the cell", there are no active method steps in the claim and thus does not result in the production of a polypeptide that differs in scope from the polypeptide of claim 27. Amending the claim in a proper product-by-process form would be remedial.

***Claim Rejections - 35 USC § 101 and 35 USC §112, 1<sup>st</sup> Paragraph***

12. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 25, 27, 29-30, 32-34, 37-38, and 41-42 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Novel biological molecules lack an established utility and must undergo extensive experimentation to determine an appropriate specific and substantial utility.

14. Specifically, claims 25, 27, 29-30, 32-34, 37-38, and 41-42 are directed to an isolated mammalian polypeptide comprising the sequence of SEQ ID NO:1 or SEQ ID NO:21, and variant polypeptides corresponding to SEQ ID NO:1 or SEQ ID NO:21, in which one or more amino acids are replaced, deleted, inserted and/or added, and an isolated mammalian polypeptide encoded by the nucleic acid sequence of SEQ ID NO:5 or variant nucleic acid that encode for variant polypeptide corresponding to SEQ ID NO:1. The claims also recite the polypeptide contained in a suitable pharmaceutical composition for delivery to a subject, the polypeptide comprising one or more antigenic polypeptide sequences, and wherein the polypeptide binds to a binding partner located on a cell membrane with a  $K_d$  of approximately  $10^{-8}M$  or greater, and wherein said binding produces a molecular signal that is transmitted to the interior of the cell.

15. The Specification teaches an isolated hHSS1 polypeptide comprising the amino acid sequence SEQ ID NO:1 (full-length immature form) and SEQ ID NO:21 (mature form). The Specification also discloses an isolated hHSM1 polypeptide comprising the amino acid sequence (SEQ ID NO:2) which the Specification asserts is a related membrane-bound splice variant (See pg 2, lines 2-4). The Specification further asserts that the presence of a secreted form and

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membrane-bound form is a biologically relevant functional motif that has been reported in other systems that have important growth and regulatory functions *in vivo* (See pg 11, lines 6-19). The Specification teaches that this previously unknown system of proteins has no structural homology to any known protein or protein class in the current protein database, yet is ubiquitously expressed in nearly all tissue types (See pg 1, line 25 through pg 2, line 1; pg 13, lines 21-29; Figure 1). However, the instant specification does not teach any physiologic ligands or functional characteristics of the hHSS1 polypeptide set forth in SEQ ID NO:1 or the nucleic acid molecule (SEQ ID NO:5) encoding it. There is no well-established utility for a specific hHSS1 nucleic acid or amino acid sequence, and the specification fails to disclose a specific and substantial utility for the claimed invention. The instant application does not disclose a specific biological role for the hHSS1 protein or nucleic acid molecule or its significance to a particular disease, disorder, or physiological process which one would manipulate for a desired physiological or clinical effect.

16. Based on ubiquitous tissue distribution and the presence of both secreted and membrane-bound forms of the polypeptide, the specification asserts the following as patentable utilities for the claimed hHSS1 polypeptides of SEQ ID NO:1 and SEQ ID NO:21:

- a.) screening for a compound or cell types that bind to the polypeptide (See pg 5, lines 18-24;
- b.) generating antibodies (See pg 33, lines 8-9;
- c.) treatment of conditions associated with abnormal physiology or development, including abnormal proliferation, e.g., cancerous conditions or degenerative conditions (See pg 42, lines 17-22, pg 44, lines 14-16; and

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d.) Identification of agonists and antagonists which can be used in treatment (See pg 42, lines 22-26);

17. These asserted utilities are neither specific nor substantial because they do not identify or reasonably confirm a “real world” context of use. The specification neither identifies the biological functions of the claimed the hHSS1 polypeptide or the nucleic acid encoding it, nor any diseases that are associated with the claimed molecules. Moreover, there does not appear to be sufficient evidence to support the assertion that the hHSS1 polypeptide or the nucleic acid encoding it is associated in any way with any condition associated with abnormal physiology or development, including abnormal proliferation, e.g., cancerous conditions or degenerative conditions. Without any biological activity or link to a disease, such constitutes further research to determine the properties of the claimed hHSS1 polypeptides, which is insufficient to meet the requirement of 35 USC § 101.

18. Utility must be in readily available form. It is possible that, after further characterization, this nucleic acid and the encoded protein might be found to have a patentable utility, in which case the proteins would have a specific utility, or the protein might be found to be associated with a specific disease or disorder. This further characterization, however, is part of the act of invention, and until it has been undertaken, Applicant's claimed invention is incomplete. Furthermore, whereas one could readily employ the hHSS1 polypeptide of SEQ ID NO:1 of the instant invention in an assay to identify modulators (agonists and antagonists) thereof, the information obtained from such assays would be of little use until one discovers the identity of those physiological processes moderated by the hHSS1 polypeptide. Because the instant specification has failed to identify a physiological process which has been shown to be

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influenced by the hHSS1 protein of the instant invention, an artisan would have no way of predicting what effects the administration of that protein to an organism would have. If one cannot predict the effects that the administration of the hHSS1 protein of the instant invention is going to have on an organism, then it is unclear as to what practical or real world benefit is derived by the public from the identification of protein.

19. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

In the Instant case, the instant specification leaves it to the practitioner to discover the identity of a disease or disorder in which the polynucleotide or protein encoded thereby of the instant invention is mutated or aberrantly expressed, and to discover the nature of that aberrant

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expression (i.e., overexpression or underexpression). The evidence of both secreted and membrane-bound forms of the polypeptide and ubiquitous expression in nearly all tissue types is not tantamount to a showing of a role of the hHSS1 polypeptide of SEQ ID NO:1 in a disease/disorder, or that the polynucleotides or polypeptides are useful modulating a biological activity or in the treatment of a disease or disorder. Therefore, the claimed polypeptides cannot be used in a therapeutic capacity without the need for a substantial inventive contribution. Such additional experimentation, if needed to identify a specific utility for an invention, is precluded by the court.

20. Claims 25, 27, 29-30, 32-34, 37-38, and 41-42 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make/use the claimed invention.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph (Scope of Enablement)***

21. However, even if the claimed invention is eventually deemed to have a credible, specific and substantial asserted utility or a well established utility, claims 25, 27, 29-30, 32-34, 37-38, and 41-42 would remain rejected under 35 U.S.C. § 112, first paragraph because the instant disclosure would not be found to be enabling for the full scope of the claimed invention.

22. The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of

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direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

23. The claims are drawn quite broadly to an isolated mammalian polypeptide comprising the sequence of SEQ ID NO:1 or SEQ ID NO:21, and variant polypeptides corresponding to SEQ ID NO:1 or SEQ ID NO:21, in which one or more amino acids are replaced, deleted, inserted and/or added, and an isolated mammalian polypeptide encoded by the nucleic acid sequence of SEQ ID NO:5 or variant nucleic acid that encode for variant polypeptide corresponding to SEQ ID NO:1. The claims also recite the polypeptide contained in a suitable pharmaceutical composition for delivery to a subject, the polypeptide comprising one or more antigenic polypeptide sequences, and wherein the polypeptide binds to a binding partner located on a cell membrane with a  $K_d$  of approximately  $10^{-8}M$  or greater, and wherein said binding produces a molecular signal that is transmitted to the interior of the cell. However, other than the polynucleotide of SEQ ID NO:1 and SEQ ID NO:21, the disclosure fails to provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. The disclosure has not shown (1) which portions of the protein of SEQ ID NO:1 are critical to the activity of the protein of SEQ ID NO:1 (which is itself unknown); (2) what modifications e.g., substitutions, deletions, or additions) one can make to SEQ ID NO:1 that will result in protein mutants or variants with the same function/activity as the protein of SEQ ID NO:1; and (3) any guidance on how to use the variants of SEQ ID NO:1 which would, based on the language of said claims, encompass both active and inactive variants, especially in the absence of any functional limitations in the claims. The state of the art is such that the relationship between the sequence of a protein and its activity is not well understood and

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unpredictable, and that certain positions in the sequence are critical to the protein's structure/function relationship and can only tolerate only relatively conservative substitutions or no substitutions.

24. The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and DNA is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, *Biochemistry* 29:8509-8517; Ngo et al., 1994, *The Protein Folding Problem and Tertiary Structure Prediction*, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions and still retain the activity of the protein of SEQ ID NO:1. Furthermore, claim 37 recites wherein the polypeptide binds to a binding partner located on a cell membrane with a  $K_d$  of approximately  $10^{-8}M$  or greater, and claim 38 recites wherein the binding produces a molecular signal that is transmitted to the interior of the cell. However, the Specification does not teach any binding partner to which the claimed polypeptide binds, nor does it teach that the

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claimed polypeptides elicit a molecular signal that is transmitted to the interior of a cell. Therefore, mere recitation of “wherein the polypeptide binds to a binding partner located on a cell membrane with a  $K_d$  of approximately  $10^{-8}M$  or greater”, and “wherein the binding produces a molecular signal that is transmitted to the interior of the cell” is not sufficient to enable the broad scope of the claimed molecules.

25. Furthermore, claim 29 is drawn to a pharmaceutical composition for delivery to a subject. However, the specification as filed does not provide adequate guidance on how to treat or prevent any disease or condition by the administration of the polypeptide of SEQ ID NO:1, nor is it at all predictable that a pharmaceutical composition comprising the polypeptide of SEQ ID NO:1 could be used to treat or prevent any disease or condition. With regards to this portion of the rejection, amendment of claim 29 to recite, for example, “A composition comprising the polypeptide of claim 25 and a pharmaceutically acceptable carrier” would be remedial.

26. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph (Written Description)***

27. Claims 25, 27, 29-30, 32-34, 37-38, and 41-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

28. Claims 25, 27, 29-30, 32-34, 37-38, and 41-42 are drawn quite broadly to an isolated mammalian polypeptide comprising the sequence of SEQ ID NO:1 or SEQ ID NO:21, and variant polypeptides corresponding to SEQ ID NO:1 or SEQ ID NO:21, in which one or more amino acids are replaced, deleted, inserted and/or added, and an isolated mammalian polypeptide encoded by the nucleic acid sequence of SEQ ID NO:5 or variant nucleic acid that encode for variant polypeptide corresponding to SEQ ID NO:1. The claims also recite the polypeptide contained in a suitable pharmaceutical composition for delivery to a subject, the polypeptide comprising one or more antigenic polypeptide sequences, and wherein the polypeptide binds to a binding partner located on a cell membrane with a  $K_d$  of approximately  $10^{-8}M$  or greater, and wherein said binding produces a molecular signal that is transmitted to the interior of the cell. Thus, the claims are drawn to a genus of polypeptides that are defined only by a partial structure.

29. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of “variant polypeptides corresponding to

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SEQ ID NO:1. There is not even identification of any particular portion of the structure that must be conserved.

30. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Additionally, the description of two polypeptide species (SEQ ID NO:1 and SEQ ID NO:21) and one polynucleotide species (SEQ ID NO:5) is not adequate written description of an entire genus of functionally polypeptides, which incorporate all variants, derivatives, and homologs encompassed by the claims. Furthermore, claim 37 recites wherein the polypeptide binds to a binding partner located on a cell membrane with a  $K_d$  of approximately  $10^{-8}M$  or greater, and claim 38 recites wherein the binding produces a molecular signal that is transmitted to the interior of the cell. However, the Specification does not teach any binding partner to which the claimed polypeptide binds, nor does it teach that the claimed polypeptides elicit a molecular signal that is transmitted to the interior of a cell. Therefore, mere recitation of “wherein the polypeptide binds to a binding partner located on a cell membrane with a  $K_d$  of approximately  $10^{-8}M$  or greater”, and “wherein the binding produces a molecular signal that is transmitted to the interior of the cell” does not provide adequate written description for the broad scope of the claimed molecules.

31. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*” (See page 1117). The specification does not “clearly allow persons of

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ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

32. With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

33. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

34. Therefore, only an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:1 or SEQ ID NO:21, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

### ***Claim Rejections - 35 USC § 112***

35. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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36. Claims 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

37. Claim 41 recites the limitation "the nucleic acid sequence corresponding to the peptide". There is insufficient antecedent basis for this limitation in the claim. Claim 27, from which claim 41 depends, does not recite a "nucleic acid sequence corresponding to the peptide". Amending the claim to recite, for example, "wherein the nucleic acid sequence encoding the polypeptide", would be remedial.

38. Claim 42 recites the limitation "wherein the expressed polypeptide". There is insufficient antecedent basis for this limitation in the claim. Claim 41, from which claim 42 depends, does not recite an "expressed polypeptide".

### ***Claim Rejections - 35 USC § 102***

39. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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40. Claims 25, 27, 29-30, 32-34, 41, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (US 2003/0073129 A1, filed 04 September 2001; previously cited by Examiner).

41. Baker et al teach an isolated mammalian polypeptide (PRO1556) comprising the amino acid sequence SEQ ID NO:372 that shares 90% sequence identity to SEQ ID NO:1 of the Instant Application (See attached sequence alignment). Baker et al. also teach compositions comprising the PRO1556 polypeptide and a pharmaceutically acceptable carrier (See pg 142[2345], pg 212[3287] to pg 213[3289]). It is noted that the recitation in claim 29 of “for delivery to a subject...” has been interpreted as an intended use and has not been given patentable weight in this art rejection. Since Baker et al. teach antibodies which specifically bind the PRO1556 polypeptide (See pg 142[2343]), the PRO1556 polypeptide would inherently comprise an antigenic polypeptide sequence. Thus, claims 25, 27, 29-30, 32-34, 41, and 42 are anticipated by the Baker et al. reference.

### *Summary*

42. No claim is allowed.

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*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. L./  
Examiner, Art Unit 1647  
January 22, 2008

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